K083862
P. 1/7

PREMARKET NOTIFICATION 510(k) SUMMARY
As required by 21 CFR §807.92(c)

JUN - 5 2009

Submitter

510(k) Owner:	MedApps, Inc.
Owner / Operator:	10027842
Registration:	3005916763
Address:	7975 North Hayden Road, Suite A-200, Scottsdale, AZ 85258
Telephone:	480-305-6323
Fax Number:	480-393-1892
Contact Person:	Kent Dicks
Contact Person Title:	President / CEO
Date Prepared:	December 23, 2008

Device Information

Trade Name:	MedApps 2.0 - Remote Patient Monitoring System
Common Name:	Remote Patient Monitoring System
Classification Status:	Class II per regulations 870.2910
Classification Name:	Transmitters and Receivers, Physiological Signal, Radiofrequency (21 CFR 870.2910, Product Code DRG)

A. LEGALLY MARKETED PREDICATE DEVICE

Legally marketed predicate device are:

K080798	Intel Health Guide PHS6000
K072698	Confidant 2.5
K062377	MedApps Remote Patient Monitoring System (D-PAL)

B. DEVICE DESCRIPTION

The MedApps 2.0 - Remote Patient Monitoring System consists of a patient device, MedApps HealthPAL, which is a mobile Over-The-Counter wireless communication hub that connects to commercially available wireless and tethered Glucose Meters, Scales, Blood Pressure Monitors and Pulse Oximeters. The HealthPAL stores and displays the information on the OLED screen, and transmits the information to the MedApps secure host server called "HealthCOM" using off the shelf FCC approved wireless / cellular connectivity (including, but not limited to GSM, CDMA and WiMax). Healthcare professionals can review the transmitted information within the MedApps HealthCOM system, set thresholds to flag readings based on specific thresholds being exceeded. In addition, the MedApps Interactive Voice Response (IVR) has the ability to contact the patient remotely and use pre-approved ("canned") educational or reminder messages. ("Your nurse would like to talk to you, can I connect you now", "We haven't received a reading from you today, please send us your readings").

The HealthCOM system allows the patient to login and create a personal account. The patient can specify / authorize which Personal Health Record (PHR) or Electronic Health Record (EHR / EMR) they would like to send / view their data within, outside of the HealthCOM system.

The MedApps 2.0 - Remote Patient Monitoring System uses MedApps Accessories that help the patient in usability of the product, including HealthLINK which docks the HealthPAL, and HealthPOD which connects to off the shelf medical devices via their data port to transmit data via wireless or RF technology (including, but not limited to bluetooth, zigbee, ANT, ULP, etc.).

The MedApps 2.0 - Remote Patient Monitoring System consists of:

(1) MedApps HealthPAL hardware:

The physical component of the MedApps HealthPAL is an electronic device contained in a plastic enclosure with an OLED screen, built-in M2M cellular chip, speaker, smart cable connection, smart cables, wireless, LED Lights to indicate activity, timer button to remind the patient to take their reading in X minutes, last reading button, volume up and down buttons.

(2) MedApps HealthPAL software application:

The software application captures, stores and transmits information to the MedApps HealthCOM server, via the embedded communication chip / platform.

The software application takes in additional information via the embedded wireless module from other medical devices that are wireless enabled, and that have been paired to the MedApps HealthPAL.

The software application has many additional functions including:

- Download of the users profile from the server to configure the HealthPAL remotely.
- Ability to "talk" to the patient with verbal acknowledgments of readings from all attached medical devices, time settings, volume control, educational content and reminders, in any language that is loaded to the device.
- Timer set that was activated by the user at a set timeframe to do whatever they wanted to be reminded to do.
- Control the OLED screen to show certain information including, battery status, volume level, transmission status, message waiting indicator, medical device last reading, activity icons / messages and more as it pertains to provide ease of use and easier adoption for the patient.
- Battery charging, isolation circuits, and interfaces to individual medical devices / protocols via the smart cables.

- For complete comparison of predicate devices see paragraph D - TECHNOLOGICAL CHARACTERISTICS SUMMARY table below. Additionally, please reference Exhibit 08 - System Requirements Specifications (FDA-SRS-8009) document for complete software / system functionality.

(3) MedApps HealthLINK hardware / software:

The HealthLINK hardware / software plugs into off the shelf Glucose Meters, Scales, Blood Pressure Monitors and Pulse Oximeters, and transmit the data via wireless to a receiver that it is already paired with. This functionality was cleared in the MedApps D-PAL submission K062377 in July 2007.

(4) MedApps HealthPOD hardware / software:

The HealthPOD hardware / software is an extension of the HealthPAL functionality that is outlined in this submission. HealthPOD acts as a "docking" station for the HealthPAL in order to recharge batteries, take in additional connections to off the shelf Glucose Meters, Scales, Blood Pressure Monitors and Pulse Oximeters, via smart cables (per validated in HealthPAL software), add a backup communication method via phone line (POTS line), and communicate via wireless to HealthPAL or additional HealthPODs.

(5) MedApps HealthCOM software application:

The software application allows caregivers to set thresholds and review patient data on the secure HealthCOM website.

The HealthCOM software also allows the patient to establish an account and to direct / authorize their data to be directed to an outside, validated Personal Health Record (PHR), Electronic Health Record (EHR or EMR).

(6) MedApps IVR software application:

The software application calls the patient on any phone that is designated in their user profile, and executes an approved ("canned") script to gather information. ("Your nurse would like to talk to you, can I connect you now", "We haven't received a reading from you today, please send us your readings").

In addition, the MedApps IVR application will send out Email, SMS / Text Messages, Paging, IM and many other forms of communications in order to contact patients or caregivers. This will include reminders and alerts, based on parameters / thresholds set in the HealthCOM system.

C. INDICATIONS FOR USE

The MedApps 2.0 - Remote Patient Monitoring System consists of a patient device, MedApps HealthPAL, which is a mobile Over-The-Counter wireless communication hub that connects to commercially available wireless and tethered Glucose Meters, Scales, Blood Pressure Monitors and Pulse Oximeters. The HealthPAL stores and displays the information on the OLED screen, and transmits the information to the MedApps secure host server called "HealthCOM" using off the shelf FCC approved wireless / cellular connectivity (including, but not limited to GSM, CDMA and WiMax). Healthcare professionals can review the transmitted information within the MedApps HealthCOM system, set thresholds to flag readings based on specific thresholds being exceeded. In addition, the MedApps Interactive Voice Response (IVR) has the ability to contact the patient remotely and use pre-approved ("canned") educational or reminder messages. ("Your nurse would like to talk to you, can I connect you now", "We haven't received a reading from you today, please send us your readings").

The MedApps 2.0 - Remote Patient Monitoring System is not intended for diagnosis or as a substitute for medical care, and it is not intended to provide real time data. The data is made available to the patients when time-critical care is not required. The device is contraindicated for patients requiring direct medical supervision or emergency intervention.

D. TECHNOLOGICAL CHARACTERISTICS SUMMARY – as required by 807.92(a)(6)

Feature	**Intel Health Guide PHS6000** **K080798**	**Confidant 2.5** **K072698**	**MedApps Submission** **K083862**
Indications of Use	Enables healthcare providers to monitor and manage chronic conditions of patients remotely	Same	Same
Intended Use	Telemedicine System	Same	Same
Intended Users	Home users and Healthcare providers	Same	Same
Site of Use	Home (HealthPAL), Clinic (HealthCOM)	Same	Same
Data Collection Software	Intel Care Management Suite Software	The Hermes Proprietary Software	MedApps Proprietary Software

Feature	Intel Health Guide PHS6000 K080798	Confidant 2.5 K072698	MedApps Submission K083862
Data Collection Software Functionality	Transmit data from Sensor devices to Central Database	Same	Same
Communication method of hub with Central Server	Via DSL or Phone Line Connection	Via Cellular Phone	Via Embedded Cellular Technology
Types of sensors which can be interfaced (wired or wirelessly) to receiver hub	Medical Devices designed for Home: Glucose Scale Blood Pressure Pulse Ox Peak Flow	Medical Devices designed for Home: Glucose Scale Blood Pressure	Medical Devices designed for Home: Glucose Scale Blood Pressure Pulse Ox
Maximum number and type of measurement devices that can be connected to the devices	Determined by vital sign devices that are designed for Home use, and have a data port. (Wireless or Wired)	Same	Same
Maximum data throughput under worst case conditions	Multiple readings are stored on the medical devices and act as a backup if data needs to be re-sent to the server	Same	Same
Time Delay in the processing of data collected and transmitted	Readings stored in the medical devices can be sent up to the server when the connection is restored.	Same	Same
Implementation method of collecting data from sensors	Short range radio system using Bluetooth and Wired (tethered) cables.	Short range radio system using Bluetooth	Short range radio system using Bluetooth and Wired (tethered) cables.
Sensor Software	Sensor Software unchanged	Same	Same
Connectivity	Short range radio system using Bluetooth and Wired (tethered) cables.	Short range radio system using Bluetooth	Short range radio system using Bluetooth and Wired (tethered) cables.
Communication method of hub with devices	Short range radio system using Bluetooth and Wired (tethered) cables.	Short range radio system using Bluetooth	Short range radio system using Bluetooth and Wired (tethered) cables.

Feature	Intel Health Guide PHS6000 K080798	Confidant 2.5 K072698	MedApps Submission K083862
Communications Protocol	Bluetooth V2.0 and Wired (Tethered)	Bluetooth V2.0	Bluetooth V2.0 and Wired (Tethered)
Communication Frequency	Bluetooth : 2.402 to 2.480 GHz	Bluetooth : 2.402 to 2.480 GHz GSM: 850 / 900 / 1800 / 1950 Mhz	Bluetooth : 2.402 to 2.480 GHz GSM: 850 / 900 / 1800 / 1950 Mhz
Power Source	Wall power plug (120 VAC/50-60)	Wall power plug (120 VAC/50-60) and Rechargeable Batteries in Device	Wall power plug (120 VAC/50-60) and Rechargeable Batteries in Device
Display	On devices and hub, and monitors connected to central server	Same	Same
Communication with Patients	On screen display	Same	On screen display of Readings, Voice Output and Interactive Voice Response (IVR)
Use of Thresholds / Algorithms for determining how Thresholds are set and changed	Thresholds are set by Healthcare professionals in Server Software	Same	Same
Information presented to the user, if it is different from that presented by the measurement devices	On screen display	Same	On screen display of Readings, Voice Output and Interactive Voice Response (IVR)
Messages and Instructions that can be sent to the User.	On screen display	Same	On screen display of Readings, Voice Output and Interactive Voice Response (IVR)

Data Collection:
The 2 predicates and the MedApps solution connect to medical devices (designed for home use) via either through wired (cable) or wireless (bluetooth). The data is collected from the devices and sent up to the central server via various communication methods.

Telecommunication Platform to Central Server:
Intel Health uses DSL connectivity (wired point of care), Confidant uses an off the shelf Cell Phone (Cellular), and MedApps uses an embedded Machine to Machine (M2M) module that transmits the data via cellular connectivity.

Patient Feedback Technology:
On the 2 predicates and MedApps, data and messages are displayed on a screen for the patient to read and acknowledge. The MedApps solution also uses an Interactive Voice Response (IVR) system in order to call up the patient and ask them a question, or remind them to take their readings.

Backend Data Storage:
All systems (2 predicates and MedApps), have a backend system that allows data to be stored, and for Healthcare professionals to have the ability to monitor the patients data.

E. NON-CLINICAL PERFORMANCE DATA TESTING AND REVIEW – as required by 807.92(b)(1)

Non-Clinical Testing
The submitted device has undergone significant verification and validation testing. Alpha validation testing included testing of all executable code and functionality and confirmation that all identified hazards have been adequately addressed by software functionality, the user interface, documentation or user SOP.

Alpha validation activities included exhaustive validation scripts of all Detail Design Specifications (DDS), which was summarized and discussed to provide a preliminary record of performance data. Additionally, the submitter duplicated the operational environment of a sophisticated user and provided the complete record of those executed scripts as operational performance data. The output of these two performance data records documents that **MedApps 2.0 - Remote Patient Monitoring System** met its required requirements and design specifications as intended.

F. SUBSTANTIAL EQUIVALENT

The MedApps Remote Patient Monitoring System 2.0 is substantially equivalent to the predicate devices in terms of data collection software functionality, operating system for the patient device, communication method of patient device with central server, types of sensors which can be interfaced to the patient device, implementation method of collecting data from sensors, sensor software, connectivity, communication protocol, power source and display method.

G. SAFETY AND EFFICACY

The MedApps Remote Patient Monitoring System 2.0 does not rely on an assessment of clinical performance data. The device conforms to FDA's recognized consensus standards and relies on its conformity to demonstrate its safety and efficacy. The device introduces no new questions concerning the safety or efficacy and is, therefore, substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 5 2009

MedApps, Inc.
c/o Mr. Kent Dicks
President & CEO
7975 North Hayden Road, Suite A-200
Scottsdale, AZ 85258

Re: K083862
Trade/Device Name: MedApps 2.0 Remote Patient Monitoring System
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency physiological signal transmitter and receiver
Regulatory Class: Class II
Product Code: DRG
Dated: March 31, 2009
Received: April 1, 2009

Dear Mr. Dicks:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

MedApps, Inc.
STATEMENT OF INDICATIONS FOR USE

EXHIBIT 01

510(k) Number: K083862

Preparation Date: December 23, 2008

Device Name: **MedApps 2.0 - Remote Patient Monitoring System**

Indications For Use:

The MedApps 2.0 - Remote Patient Monitoring System consists of a patient device, MedApps HealthPAL, which is a mobile Over-The-Counter wireless communication hub that connects to commercially available wireless and tethered Glucose Meters, Scales, Blood Pressure Monitors and Pulse Oximeters. The HealthPAL stores and displays the information on the OLED screen, and transmits the information to the MedApps secure host server called "HealthCOM" using off the shelf FCC approved wireless / cellular connectivity (including, but not limited to GSM, CDMA and WiMax). Healthcare professionals can review the transmitted information within the MedApps HealthCOM system, set thresholds to flag readings based on specific thresholds being exceeded. In addition, the MedApps Interactive Voice Response (IVR) has the ability to contact the patient remotely and use pre-approved ("canned") educational or reminder messages. ("Your nurse would like to talk to you, can I connect you now", "We haven't received a reading from you today, please send us your readings").

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(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use X
(Per 21 CFR 801.109)

Donna R. Mitchell

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K083862